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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/826,966

04/16/2004

James McSwiggen

03-465-D (400/151)

2134

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06/08/2007

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EXAMINER

GIBBS, TERRA C

ART UNIT

PAPER NUMBER

1635

MAIL DATE

DELIVERY MODE

06/08/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/826,966

Applicant(s)

MCSWIGGEN ET AL.

Examiner

Terra C. Gibbs

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3,14-21,30,31 and 33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,14-21,30,31 and 33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>May 1, 2007 and May 3, 2007</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This Office Action is a response to Applicant's Amendment and Remarks filed March 23, 2007.

Claims 1, 31, and 33 have been amended.

Claims 1, 3, 14-21, 30, 31, and 33 are pending in the instant application.

Claims 1, 3, 14-21, 30, 31, and 33 have been examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Information Disclosure Statement***

Applicant's information disclosure statement filed May 1, 2007 is acknowledged. It is noted that the Examiner has only considered the Abstract of Documents 1-4. The submission is in compliance with the provisions of 37 CFR §1.97. Accordingly, the Examiner has considered the information disclosure statement, and a signed copy is enclosed herewith.

Applicant's information disclosure statement filed May 3, 2007 is acknowledged. The submission is in compliance with the provisions of 37 CFR §1.97. Accordingly, the Examiner has considered the information disclosure statement, and a signed copy is enclosed herewith.

### ***Specification***

In the previous Office Action mailed October 24, 2006, it was noted that the

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amendment filed October 2, 2006 was objected to under 35 U.S.C. 132(a) because it introduced new matter into the disclosure. **This objection is withdrawn** in view of Applicant's Amendment to the Sequence Listing and Applicant's Remarks filed March 23, 2007. Specifically, the Examiner is withdrawing this objection in view of Applicant's Amendment to the Sequence Listing to recite thymidine residues rather than uracil residues. The Examiner is also withdrawing this objection in view of Applicant's Remarks that GenBank Accession Number AF100308 is the same sequence as AF100308.1. The Examiner acknowledges that the two sequences are one and the same, as shown at page 8 of Applicant's Remarks filed March 23, 2007.

### ***Priority***

It is noted that in the previous Office Action mailed October 24, 2006, the instant application was afforded priority to April 16, 2004, which is the filing date of the instant application because support for SEQ ID NO:674 or GenBank Accession Number AF100308 was not found in any of the later filed parent applications for which Applicants claim benefit.

### ***Response to Arguments***

In response to this action, Applicants contend that the Sequence Listing has been amended to recite thymidine residues rather than uracil residues. Applicants also contend that GenBank Accession Number AF100308 is the same sequence as AF100308.1.

These contentions have been fully considered. The Examiner acknowledges that the Sequence Listing has been amended to recite thymidine residues rather than uracil residues. The Examiner also acknowledges that GenBank Accession Number AF100308 is one and the same sequence as AF100308.1, as shown at page 8 of Applicant's Remarks filed March 23, 2007.

It is further noted the instant claims have been amended and are currently drawn to a chemically modified double stranded short interfering nucleic acid (siNA) molecule comprising a sense strand and an antisense strand, wherein the antisense strand is complementary to a portion of an hepatitis B virus (HBV) encoded by SEQ ID NO:674.

Applicants contend that support for the present claims can be found throughout priority application 60/358,580. Applicants point the Examiner particularly to pages 5-11 of the priority application.

Now then, referring to pages 5-11 of Provisional Application No. 60/358,580, the Examiner cannot find support for the term, "short interfering nucleic acid (siNA) molecule". While the term, "short interfering RNA (siRNA) molecule" appears to be supported, "siNA" does not appear to be recited anywhere in Provisional Application No. 60/358,580.

In summary, none of the parent applications, including Provisional Application No. 60/358,580 appear to have support for a chemically modified double stranded short interfering nucleic acid (siNA) molecule comprising a sense strand and an antisense strand, wherein the antisense strand is complementary to a portion of an hepatitis B virus (HBV) encoded by SEQ ID NO:674 as instantly claimed. In this regard, the instant

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claims have been afforded priority to the filing date of the instant application, which is April 16, 2004.

If Applicants believe that they are entitled to an earlier priority date, the Examiner urges Applicant to specifically point where support can be found for a "short interfering nucleic acid (siNA) molecule" in any other applications Applicants claim priority to.

### ***Claim Objections***

In the previous Office Action mailed October 24, 2006, claim 31 was objected to because of minor informalities. **This objection is withdrawn** in view of Applicant's Amendment to claim 31 filed March 23, 2007. Specifically, the Examiner is withdrawing this objection in view of Applicant's Amendment to the claim to recite, "A composition comprising the siNA molecule of claim 1 in a pharmaceutically acceptable carrier or diluent".

### ***Claim Rejections - 35 USC § 112***

In the previous Office Action mailed October 24, 2006, claim 33 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **This rejection is withdrawn** in view of Applicant's Amendment to claim 33 filed March 23, 2007. Specifically, the Examiner is withdrawing this rejection in view of Applicant's Amendment to claim 33 to correct for insufficient antecedent basis.

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In the previous Office Action mailed October 24, 2006, claims 1, 3, 14-21, 30, 31, and 33 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. This was a written description rejection. **This rejection is withdrawn** in view of Applicant's Amendment to the Sequence Listing and Applicant's Remarks filed March 23, 2007. Specifically, the Examiner is withdrawing this rejection in view of Applicant's Amendment to the Sequence Listing to recite thymidine residues rather than uracil residues. The Examiner is also withdrawing this rejection in view of Applicant's Remarks that GenBank Accession Number AF100308 is the same sequence as AF100308.1. The Examiner acknowledges that the two sequences are one and the same, as shown at page 8 of Applicant's Remarks filed March 23, 2007.

***Claim Rejections - 35 USC § 103***

In the previous Office Action mailed October 24, 2006, claims 1, 3, 14-21, 30, 31, and 33 were rejected under 35 U.S.C. 103(a) as being unpatentable over GenBank Accession Number AF100308 (submitted and made of record on the information disclosure statement filed August 13, 2004), in view of Hamasaki et al. (FEBS Letters, 2003 Vol. 354 :51-54), Braasch et al. (Biochemistry, 2003 Vol. 42 :7967-7975), Elbashir et al. (submitted and made of record on the information disclosure statement filed August 13, 2004), Matulic-Adamic et al. (US Patent No. 5,998,203), and/or Parrish et al. (submitted and made of record on the information disclosure statement filed August 13, 2004). **This rejection is maintained** for the reasons of record set forth in the previous

Office Action mailed October 24, 2006.

***Response to Arguments***

In response to this rejection, Applicants argue that because SEQ ID NO:674 and GenBank entry AF100308.1 is supported in priority application 60/358,580, the present application is entitled to the priority date of Provisional Application No. 60/358,580, which is February 20, 2002. In this regard, Applicants contend that Hamasaki et al. and Braasch et al. are not prior art to the present application and thus the instant rejection should be withdrawn.

Applicant's arguments and contentions have been fully considered but are not found persuasive because, as discussed above, the instant application has not been afforded priority to February 20, 2002, which is the priority date for Provisional Application No. 60/358,580 because this application does not appear to have support for a chemically modified double stranded short interfering nucleic acid (siNA) molecule comprising a sense strand and an antisense strand, wherein the antisense strand is complementary to a portion of an hepatitis B virus (HBV) encoded by SEQ ID NO:674 as instantly claimed. In this regard, the instant application has been afforded priority to the filing date of the instant application, which is April 16, 2004.

In summary, Hamasaki et al. and Braasch et al. are prior art to the present application and claims 1, 3, 14-21, 30, 31, and 33 remain rejected under 35 U.S.C. 103(a) as being unpatentable over GenBank Accession Number AF100308 (submitted and made of record on the information disclosure statement filed August 13, 2004), in



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view of Hamasaki et al. (FEBS Letters, 2003 Vol. 354 :51-54), Braasch et al. (Biochemistry, 2003 Vol. 42 :7967-7975), Elbashir et al. (submitted and made of record on the information disclosure statement filed August 13, 2004), Matulic-Adamic et al. (US Patent No. 5,998,203), and/or Parrish et al. (submitted and made of record on the information disclosure statement filed August 13, 2004).

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached on 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

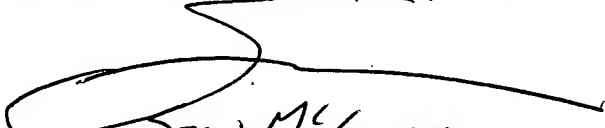
supervisor, James Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

tcg  
June 1, 2007

  
SEAN MCGARRA  
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